

SPL Process ER/DL Meeting

Meeting Minutes

June 18, 2014

Chair of today's meeting: Pat Cowall-Hanover

Teleconference information:

USA Toll-Free 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Teleconference information: How to mute/unmute

#6: Mute

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Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

Agenda:

1. NDC codes when supply components change (Van Duong)

Do you have to change the NDC number if you change the number of supplies in a kit (eg alcohol swabs, needles, etc). The drug product isn't changing. Our immediate response is that a new NDC should be assigned so that you can identify the contents of a kit. Please share actual experience.

Scenario:

The supplies that accompany the drug product in a carton package are being updated (changed from a supply "A" to a different supply "B"). In the USPI, the carton contents of the packaged product are listed individually under *Section 16 How Supplied* by NDC number. There is no change to the quantity of drug product itself. But understand that due to exhaustion of the inventory and expiry dates of package with supply A, both packaged products containing either supply A or supply B will most likely be on the market simultaneously for a period of time.

- With the change from supply A to a totally different supply B, is a new NDC required on the packaged product for drug-listing purpose?
- If a new NDC is required, both packaged products (both NDCs) will be drug-listed in SPL. How do we specify the "Marketing Start Date" in SPL if we plan to launch the packaging containing supply B several months after FDA approval (due to exhaustion of the inventory with supply A)?
- If a new NDC is NOT required, do we just change the information in *Section 16 How Supplied* of the USPI and SPL under the same NDC?

Meeting discussion:

The regs are pretty vague and state in 21CFR207.37(b)(4)(i) that a new NDC is needed “if any change occurs in those product characteristics that clearly distinguish one drug product version from another....” The regs then list product characteristics, not supplies.

Unless you have a reason for not assigning a new NDC code, I think it would be preferable to you and your customers to assign a new one – possibly a different pack size (last 2 digits) of the same product NDC. This is especially true since it appears that you need to get FDA approval of Kit B.

- This process will also allow you to conveniently track when kit A is exhausted....
- and allows customers to clearly order and know what they will be receiving (eg you wouldn't want people to order kit A (eg expecting to get syringe needles) and receive kit B (eg with no needles).
-and potentially allows for price differences (based on the supplies provided)
- and you can clearly specify both in your How Supplied section.

Concern: How could you clearly identify the product differences if you don't have a different NDC number.

- Would the difference be a product code or a package code? This would depend on the specific product / package configuration. In this specific case, the product is not listed as a kit (ie devices are not listed) Thus it is safe either to change or not change the NDC because the SPL metadata would be the same for each.
- New NDC code would help internal tracking and record keeping.
- If you list the other supplies in the kit, you will need to change the product NDC. If you don't list the other supplies in the kit, then the product NDC will not be affected.
- Ben Harpster: they use a new package code for each different configuration of the supplies.
- CBER – every individual package configuration needs its own NDC code.

Dates:

The market start date for Kit B can be a future date – ie you can put in a future date when you initially drug list. The new product NDC will not appear in the NDC directory until the new market start date. You can always resubmit your SPL drug listing with a revised date, if needed, once you have a better idea of when the product will actually hit the shelves.

2. Injectable products – assignment of NDC numbers for single use vials containing different amounts of drug. (Pat Cowall)

There seems to be different processes in place for assigning NDC codes for solids in a vial vs liquids in a vial. For solids, products are differentiated at the product NDC level. For solutions, some companies differentiate by using different package codes – using the logic that the concentration of the drug product is the same. The same logic can be applied to the powders in a vial – especially considering Rx norm and how we need to report the concentration in SPL data elements.

I would like to share experience/interaction with regulatory agencies. (Pat Cowall)

Examples:

- For injectable products that need to be reconstituted: 200 mg in a 10 ml vial and 1 g in a 50 ml vial.

- For injectable products that are already reconstituted: 100 mg/50 mL and 200 mg/100 mL

Meeting discussion:

Ruth Kirkner – would like to discuss further. If anyone else would like to use the NDC, the bottom line is that others would have to use the same basis of strength.

Beverly Haskill – safety consideration forto minimize safety errors. Section G. Injectable products. page 14. Marcia is sending .

Pat will report back at the next meeting

3 draft guidances. Will share links in the minutes.

3. SPL Jamboree 2014:
National Library of Medicine has announced the 2014 SPL/DailyMed Jamboree Workshop which is scheduled for Thursday, September 18, 2014, at NLM in Bethesda, MD.

More information (including the agenda) regarding this free public SPL workshop is posted on this NLM web page: http://www.nlm.nih.gov/mesh/spl_workshop_2014.html.

Meeting discussion:

4. Drug listing of NDC codes for inner kit components -- for awareness (Pat Cowall)

We recently received a letter from CMS requesting us to drug list inner components of kits. They acknowledged that these inner packs are not sold separately away from the kit. And they acknowledged that we have already included them in our SPL as part of the kit. But they need the inner NDC listed for some reason to help their system work – presumably because customers are using the inner NDC codes to request payments, instead of correctly using the outer tradepack of kits.

Pharma can comply with what CMS is requesting, but adding adding these NDCs is a work around to meet CMS needs and our drug listing data would improperly include NDC codes that are not commercially available.

I talked to Lonnie about this ongoing need of CMS and the possibility of them extracting this data into the NSDE file that prepare for CMS. Lonnie replied that this would be a possibility and that he would be glad to talk to CMS about this. I will be sending the letter we received to Lonnie so that he can initiate these conversations.

Meeting discussion:

Pat will follow up with Lonnie and report back to the group.

5. Assigning NDC codes for blister packs. (David Shilling)

For example, we market a 15 count product in which there are 5 tablets to a blister card and 3 blister cards to a carton. Each blister card encompasses 5 single use doses of blisters (a single tablet per blister unit/cavity).

Since day 1 I've managed this by:

2	NDC:41167-4120-2	3 in 1 CARTON	
2		5 in 1 BLISTER PACK	

There has never been an issue. When I tried to update the listing, though, it didn't pass validation and when I asked for an override Lonnie indicated that, "are there individual labels for each tablet? If the answer to that question is "yes," in the product data elements section, the inner level should be 1 in 1 blister pack." I guess indicating I should change to 15 in 1 blister pack and 1 in 1 carton?

I think I know where he is coming from but this doesn't seem logical. I was going to ask the team if anyone else had run into this issue before I either change or reach back out to Lonnie. (I've checked and as far as I can tell, other DLings (Zyrtec, Claritin, Contac) are described the same as I have).

Meeting notes

- We discussed this extensively in a previous meeting.
- Jackie Mohns summarized the discussion -- the key question goes to the intent of the packaging -- is the package intended to be individual blister packs - ie is it intended to be a carton of 15 or 15 individual blister packs. Key question is whether the cards are perforated (indicating that they are intended to be individual).
- Lonnie is just challenging to make sure it is drug listed correctly.

6. Sheila Vogdes AbbVie, Inc.

In the last couple of weeks the FDA review divisions have not accepted the MS Word documents that we have submitted, stating that they are not compliant with the regulations and SEALD checklist for whitespace and the lines around the Highlights headings. We use MS Word documents that are rendered from our XML file and have been using these files for almost four years. But it seems that there is an increased attention to these format issues in last few weeks.

Have other companies experienced an increase in format comments from FDA review divisions?
Do any other companies create MSWord renditions from their XML?

Meeting notes

- This is becoming a bigger issue.
- Refer to the 42 checkpoints to review before you submit the supplement .
- Jackie Mohns is providing the link. I will put the link in the minutes.

7. Marcia/Stacey M. St.Clair, RAC, EDA

I work for Fleet Laboratories, in Virginia, and we manufacture OTC drugs. We are having trouble obtaining a CPP for an OTC product because the international label is not on DailyMed.

Meeting notes:

- Pfizer. They have starting seeing this issue within the last several months. No strategy to how to manage.
- They drug listed it even though they don't sell the particular pack size in the US.
- No strategy has been developed.
- We thought that a CPP required that the product be sold in the US. But, the requirement may be that the product be suitable for
- Other issues are seeing this because the specific labeling is not showing up, only representative labeling is included in the SPL.
 - o Specific package/size wasn't included in the SPL
 - o We have been told not to include all package sizes.
- Resolution options:
 - o Update the SPL with more sizes
 - o Try to explain the situation to CPP and
- Marcia will follow up with the OTC representative and with Lonnie separately

8. Establishment registration: Will the effective date in a DER registration prevent the file from being updated on the DECRS website.
 - a. Response: No. A future date will not prevent the
9. Should multiple vials in a carton have the same the NDC number as the carton.
 - a. For CBER, each layer of packaging has to have a unique NDC.
 - b. For CDER, the NDC numbers can be the same if it is 1-1 situation.
For CDER if there are multiple vials in a carton the single vial and the carton should have different package NDC codes.